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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,266	01/30/2002	Charles L. Sawyers	30435.53USD4	5616
26941	7590	05/18/2004	EXAMINER	
MANDEL & ADRIANO 55 SOUTH LAKE AVENUE SUITE 710 PASADENA, CA 91101			TON, THAIAN N	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/066,266

Applicant(s)

SAWYERS ET AL.

Examiner

Thai-An N Ton

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-29 is/are pending in the application.
- 4a) Of the above claim(s) 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/29/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Claims 21-29 are pending. Claims 21-26 are under current examination.

#### *Election/Restrictions*

Applicant's election with traverse of Group I (claims 21-26) in the paper filed 4/9/04 is acknowledged. The traversal is on the ground(s) that the inventions in the three groups are related and that examination of all three groups together would not create an undue burden. This is not found persuasive because the three groups have been shown to be distinct and have acquired a separate status in the art as shown by their different classification, and because of their divergent subject matter, restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 27-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Applicants' Response, filed 4/9/04.

#### *Priority*

The priority information in the first paragraph of the specification should be updated to reflect that U.S. App. No. 09/567,202 is now U.S. Pat. No. 6,365, 797 B1, U.S. App. No. 08/951,143 is now U.S. Pat. No. 6,107,540 and U.S. App. No.

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08/732,676 is abandoned. Note further that the Applicants have submitted that that the instant application is a divisional application of App. No. 09/597,202, which is a divisional application of App. No. 08/951,143. Neither the 09/597,202 nor the 08/951,143 Applications have been restricted, and as such, it is improper to designate them as divisional applications. Appropriate correction is required.

#### *Oath/Declaration*

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it lists 08/732,676 as a U.S. provisional Application. This case is a non-provisional case.

#### *Information Disclosure Statement*

Applicants' IDS, filed 9/29/03, has been considered.

#### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 6,107,540. Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass the same methods for determining if a gene of interest has an effect on the progress of human prostate cancer. The instant claims are drawn to methods of determining if a gene of interest has an effect on the progress of human prostate cancer by introduction of the gene into an immune deficient subject mouse comprising a human prostate cancer xenograft of locally advanced or metastatic prostate cancer, transducing the cells of the xenograft *in vivo*, identifying the presence of micrometastasis or macrostasis in the subject mouse by detecting prostate cancer cells in the peripheral blood, bone marrow, bone, lymph nodes, or a site distant from the xenograft, comparing the subject mouse to a control mouse and evaluating the effect of the gene on the progression of prostate cancer by comparing cancer progression in the subject mouse and the control mouse. The '540 claim is directed to a method for assaying the effect of a gene of interest by introducing the gene of interest to an immune deficient mouse bearing a subcutaneous xenograft generated by implanting

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locally advanced or metastatic prostate cancer cells, transducing the cells of the xenograft and evaluating the presence of micrometastasis in the immune deficient mouse by detecting prostate cancer cells in the peripheral blood, bone marrow, lymph nodes, or other sites distant from the site of the xenograft, and comparing the subject mouse to a control mouse which has the subcutaneous xenograft but has not had the gene of interest introduced. Thus, the instant claims are made obvious by the '540 claim because the '540 claims which are directed to assaying an *effect* of a gene of interest encompass the embodiments of the instant claims directed to assaying for genes which minimize and facilitate the progression of prostate cancer.

Claims 21-26 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12-14 of U.S. Patent No. 6,365,797 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass methods for determining the effect of a gene on the progression of human prostate cancer in a mouse xenograft model. The instant claims are drawn to methods of determining if a gene of interest has an effect on the progress of human prostate cancer by introduction of the gene into an immune deficient subject mouse comprising a human prostate cancer xenograft of locally advanced or metastatic prostate cancer, transducing the cells of the xenograft *in vivo*, identifying the presence of micrometastasis or macrostasis in the subject mouse by detecting prostate cancer

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cells in the peripheral blood, bone marrow, bone, lymph nodes, or a site distant from the xenograft, comparing the subject mouse to a control mouse and evaluating the effect of the gene on the progression of prostate cancer by comparing cancer progression in the subject mouse and the control mouse. The '797 claims are drawn to methods for determining the effect of a gene on the progression of micrometastatic prostate cancer by transducing cells (either *in vivo* or *ex vivo*) with a gene of interest and evaluating the progression of micrometastatic cancer in the prostate cancer xenograft mouse model when compared to a control prostate cancer xenograft mouse model.

Claims 21-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-26, 29, 31, 32 and 34 of copending Application No. 10/022,115. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass methods of assessing the effect of a composition or treatment on human prostate cancer utilizing a xenograft prostate cancer mouse model. The instant claims are drawn to methods of determining if a gene of interest has an effect on the progress of human prostate cancer by introduction of the gene into an immune deficient subject mouse comprising a human prostate cancer xenograft of locally advanced or metastatic prostate cancer, transducing the cells of the xenograft *in vivo*, identifying the presence of micrometastasis or macrostasis in the

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subject mouse by detecting prostate cancer cells in the peripheral blood, bone marrow, bone, lymph nodes, or a site distant from the xenograft, comparing the subject mouse to a control mouse and evaluating the effect of the gene on the progression of prostate cancer by comparing cancer progression in the subject mouse and the control mouse. The '115 claims are drawn to methods for assessing the effect of a composition or treatment on human prostate cancer by subjecting a xenograft mouse model of prostate cancer to the composition or treatment and determining the effect on the growth of the xenograft in the mouse. IN further embodiments, the '115 claims are drawn to methods for impairing the progression of human prostate cancer by providing the an efficacious composition to a mouse bearing a human prostate cancer xenograft. The '115 specification teaches that compositions that may be used may be genetic compositions [see p. 8, lines 24-36, for example], and are thus encompassed by the term "compositions" in the claims. Accordingly, the instant claims are made obvious by the '115 claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.



Claim 21 is confusing. The claim recites that the immune deficient subject mouse comprises a human prostate cancer xenograft of locally advanced or metastatic prostate cancer issue in part (a) of the claim. It is unclear what a metastatic prostate cancer issue encompasses. Further the claim recites “or a cell suspension thereof,” in part (a) of the claim, it is unclear what the cell suspension is composed of – locally advanced prostate cancer cells? Metastatic cancer cells? Part (b) of the claim is unclear, it recites transducing the cells of the xenograft with the gene *in vivo*. It is unclear from this phrase if the transduction, the cells or the gene are *in vivo*. In part (c) of the claim, it is unclear what “the xenograft” refers to. The claim is further indefinite because it recites that the presence of micrometastasis or macrometastasis is detected in a site “distant” from the xenograft. The term “distant” is a relative term, how close or far does the site have to be to be considered distant? Appropriate correction is required. Claims 22-26 depend from claim 21.

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*Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Amy Nelson, Acting SPE of Art Unit 1632, at (571) 272-0804. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

*TNT*

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Group 1632

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